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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,043	08/21/2003	David Bebbington	VPI/00-109 DIV US	7317

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VERTEX PHARMACEUTICALS INC.
130 WAVERLY STREET
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EXAMINER

KIFLE, BRUCK

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/645,043

Applicant(s)

BEBBINGTON ET AL.

Examiner

Bruck Kifle, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22,36,37 and 39-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22 and 39-81 is/are rejected.
- 7) ☒ Claim(s) 36 and 37 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's amendments and remarks filed 12/21/04 have been received and reviewed.

Claims 22, 36, 37 and 39-81 are now pending in this application.

Terminal Disclaimer

The terminal disclaimer filed on 12/21/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent 6,689,784 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112

Claims 22 and 39-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) Regarding the definition of R² as CO₂H or an ester, or an amide thereof (or CH₂CO₂H, or an ester, or an amide thereof), Applicants point to page 12, lines 18-32 and page 13, lines 1-20 of the specification to provide support of for the ester and amides intended. The definition in these lines is open-ended. Inclusion of the groups into the claims from the specification would overcome this rejection.

The U.S. Court of claims held to this standard in *Lockheed Aircraft vs. Unites States*, 193 USPQ 449, "claims measure the invention and resolution of invention must be based on what is claimed." The CCPA said, "that invention is the subject matter defined by the claims submitted by the applicant." "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim" (*In re Priest*, 199 USPQ 11 at 15).

Therefore, Applicants need to indicate, in the claim, what is intended.

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ii) Claim 79 is an independent claim. All of the limitations of an independent claim should be within itself. Applicants need to either make claim 79 depend from claim 22 or insert all of the limitations of claim 22 into claim 79.

iii) Claim 80 is dependent on claim 79 which is an improper independent claim. Once claim 79 has been corrected, claim 80 will be a duplicate of claim 79. Appropriate correction is required.

Claims 79-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants amended list of diseases in claim 79 has been noted. However, these claims now raise additional problems. "Inflammatory disease" now embraces inflammation from any cause, not just caspase mediated ones. "Sepsis" is unclear, as it refers to two different things: 1. The presence of pathogenic organisms or their toxins in the blood or tissues. 2. The poisoned condition resulting from the presence of pathogens or their toxins, as in septicemia or septic shock. "Pancreatitis, various forms of liver and renal disease" embraces disease caused by other diseases, such as, diabetes or cancers, which has nothing to do with caspases. Again, no one has been able to treat any and all renal and liver diseases. All attempts to find a pharmaceutical to treat ALS have thus far failed indicating the difficulty of the task.

The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal is beyond the skill of practitioners in that art, *Genentech vs Novo Nordisk*, 42 USPQ2nd 1001, 1006.

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Traumatic brain injury and spinal cord injury include injuries caused by, say, car accidents as well as stroke.

The references Applicants have submitted have been considered. Sixteen of the references only have their first pages submitted. The examiner could not see the conclusions that the actual authors have reached in their own papers. Most of the remaining papers are speculative and say that more research is required.

The scope of uses embraced by these claims are not remotely enabled based solely on instant compounds ability to mediate a given caspase.

Claims 36 and 37 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,


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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle, Ph.D. whose telephone number is 571-272-0668. The examiner can normally be reached Tuesdays to Fridays between 8:30 AM and 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund J. Shah can be reached on 571-272-0674. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bruck Kifle, Ph.D.
Primary Examiner
Art Unit 1624

BK
March 11, 2005